

Applicants: Klucher et al.

Serial No.: 10/691,923

Filed: October 23, 2003

For: METHODS FOR TREATING VIRAL INFECTION USING IL-28 AND IL-29

REMARKS

Reconsideration of the application in view of the above amendments and following remarks is requested. Claims 62, 65 and 66 having been amended, the pending claims in the instant application are claims 62-66. No new matter has been added.

Applicants reserve the right to prosecute claims to cancelled subject matter in one or more continuing applications.

Information Disclosure Statement

The Examiner noted on page 2 of the Office Action that the reference, (U.S. Patent Application Serial No. 60/700,905, filed July 20, 2005) indicated in the Supplemental Information Disclosure Statement submitted by Applicants on October 25, 2005, was not cited on an accompanying 1449 form. Submitted herewith is another Supplemental Information Disclosure Statement with an accompanying 1449 form citing the aforementioned provisional patent application.

Rejection Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 62-66 under 35 U.S.C. §112, first paragraph, alleging that the specification, while being enabling for a method of reducing replication of several viruses (HBV, EMCV, BVDV AND HHV-8) *in-vitro*, by contacting said viruses with the polypeptide comprising the amino acid sequence set forth in SEQ ID NO:34, does not reasonably provide enablement for a method treating a viral infection comprising administering to an immuno-compromised mammal with a viral infection, a therapeutically effective amount of a polypeptide comprising an amino acid of SEQ ID NO:34. This rejection is respectfully traversed.

It is respectfully submitted that 35 U.S.C. §112, first paragraph, requires nothing more than disclosure which reasonably conveys to one of ordinary skill in the art how to carry out the invention commensurate with the scope of the claims. Although a patent application must provide an enabling disclosure at the time of filing, the application need not set forth all information necessary to practice the claimed invention. MPEP §2164.05(a).

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Interferons exert their antiviral biological function through induction of Interferon Stimulated Genes (ISG) (such as myxovirus resistance-1 (MxA), double-stranded RNA-dependent protein kinase (PKR) and 2-5-oligoadenylate synthetase (OAS)). To determine if IL-29 induced ISGs in liver cells and thus have anti-hepatitis activity, IL-28R α and CRF2-4 receptor expression were investigated on normal liver tissue and liver derived cell lines, such as HepG2 and HuH7. As shown in Table 4 of the specification, these liver cells displayed substantial levels of IL-28R α and CRF2-4 mRNA. The primary cell target for the hepatitis virus is the hepatocyte. As hepatocytes express both receptor components for IL-29 to signal, the next question was whether IL-29, like interferon, stimulated ISGs in liver cells. As shown in Tables 15-17 of the specification, IL-29 and pegylated IL-29 induced ISG expression in primary human hepatocytes and human liver hepatoma cell lines (HepG2 and HuH7). Furthermore, IL-29 was shown to inhibit hepatitis B viral replication in an *in vitro* assay that is generally accepted in the art as reasonably predictive of *in vivo* results (working Example 12 of the specification).

Given the amount of guidance provided by the specification, the high level of skill possessed by one of skill in the art, and the existence of several working examples, Applicants submit that the instant application clearly conveys to one of skill in the art how to carry out the claimed invention commensurate with the scope of the claims.

Because a reasonable basis to question the enablement provided for the claimed invention was not provided in the Office Action, the burden of proof under 35 U.S.C. §112, first paragraph has not been satisfied, and a *prima facie* case of lack of enablement has not been made. “A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. §112, first paragraph, unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling supports.” MPEP §2164.04. Reasons for uncertainty of the enablement are required even when there is no evidence in

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the record of operability without undue experimentation beyond the disclosed embodiments.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph, are respectfully requested.

Rejection Under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claims 62-66 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. This rejection is respectfully traversed.

The Examiner rejected claim 62, and claims 63-66 as depending from claim 62, as being indefinite for reciting "an amino acid sequence of SEQ ID NO:34." Per the Examiner's suggestion, Applicants have amended claim 62 by deleting the phrase "an amino acid sequence of SEQ ID NO:34" while replacing it with the phrase --the amino acid sequence of SEQ ID NO:34--. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph, are respectfully requested.

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Summary

In light of the above amendments and remarks, reconsideration and withdrawal of the rejections are respectfully requested. It is, thus, respectfully requested that claims 62-66 are in condition for allowance and notification to that effect is respectfully requested. If for any reason the Examiner feels that a telephone conference would expedite prosecution of the application, the Examiner is invited to telephone the undersigned at (206) 442-6540.

Respectfully Submitted,



Brian J. Walsh
Registration No. 45,543

Enclosures:

Amendment Fee Transmittal (in duplicate)
Supplemental Information Disclosure Statement
1449 form
Postcard

ZymoGenetics, Inc.
1201 Eastlake Avenue East
Seattle, WA 98102